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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,287	06/08/2006	Patricia Kwong Phieu Burnell	PB60589USw	4976
23347	7590	06/15/2009		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER EVOY, NICHOLAS LANE	
			ART UNIT 4136	PAPER NUMBER
			NOTIFICATION DATE 06/15/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,287	Applicant(s) BURNELL ET AL.	
	Examiner NICHOLAS L. EVOY	Art Unit 4136	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/2008, 7/11/2008, 6/08/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 13 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed subject matter of a computer program comprising program code does not perform a direct physical transformation and thus does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8, 11, 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., *Acoustic Measurement of Subglottic Stenosis*; Ann Otol Rhinol Laryngol 105: 1996.
4. Regarding Claim 1 and 11, Czaja et al teaches using acoustic impulse reflection imaging to measure physical and geometric characteristics of a human airway (Page 504, Paragraph 1). It is noted that Czaja et al does not teach the steps of Claim 1. However, Sexton et al disclose a method for improving lung delivery of pharmaceutical

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aerosols that includes: A method for predicting the tendency of inhaled particles to deposit within a first patient's throat when said particles are inhaled through an airway defined by said first patient's throat, said method comprising determining at least one internal physical parameter of said airway defined by the first patient's throat by means of acoustic imaging of the airway defined by the first patient's throat (Column 9, Lines 10-15); and matching said at least one internal physical parameter of the airway of the first patient's throat with a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of at least one other patient (Column 9, Lines 50-56), wherein said dataset also comprises pre-determined data relating to the tendency of said inhaled particles to deposit within said at least one other patient's throat (Column 11 Line 63 – Column 12 Line 7), and said matching thereby enables prediction of the tendency for the inhaled particles to deposit within the first patient's throat (Column 12, Lines 20-32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Czaja et al and Sexton et al, so as to create a method of improving lung delivery of pharmaceutical agents with an accurate, low cost, simple and fast such as acoustic impulse reflection imaging.

5. Regarding Claim 2, it is noted that Czaja et al does not disclose using inhaled particles that are delivered to the airway by means of an inhaler device. However, Sexton et al disclose an inhaler that acts as an aerosol drug delivery device during scanning (Column 10, Lines 20-29). It would have been obvious to one of ordinary skill

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in the art at the time the invention was made to apply the acoustic impulse reflection imaging method of Czaja et al to the inhaler and inhaled particles of Sexton et al.

6. Regarding Claim 3, it is noted that Czaja et al does not disclose using inhaled particles that comprise medicament. However, Sexton et al disclose an inhaler that acts as an aerosol drug delivery device that is capable of delivering multiple types of medicine (Column 12, Lines 7-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the acoustic impulse reflection imaging method of Czaja et al to the inhaler and inhaled medicine particles of Sexton et al.

7. Regarding Claim 4, Czaja et al disclose using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the acoustic impulse reflection imaging method of Czaja et al to the method for improving lung delivery of pharmaceutical aerosols disclosed by Sexton et al.

8. Regarding Claim 5, Czaja et al disclose using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2). However, Sexton et al disclose a method of imaging that focuses on the throat, including the pharynx and oropharynx (Column 9, Lines 3-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the imaging method of Czaja et al to the imaging location of Sexton et al because Czaja's

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method currently focuses on the laryngotracheal airway, which is comparable in anatomical structure to the pharynx and oropharynx.

9. Regarding Claim 6, Czaja et al disclose using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2). However, Sexton et al disclose a method of imaging that can determine physical characteristics of a patient's throat such as geometric alignment, spatial configuration, and volumetric descriptors and as a result geometric and spatial orientations could be determined (Column 11, Lines 42-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al and Sexton et al because it provides for anatomical imaging as disclosed in Sexton et al, but with an accurate, low cost, simple and fast imaging modality such as acoustic impulse reflection imaging

10. Regarding Claim 7, Czaja et al disclose using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2). However, Sexton et al disclose a method of imaging that makes use of a dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of at least ten other patients (Column 9, Lines 50-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al and Sexton et al because the data collected through the method of Sexton et al would also be valuable when applied to the method of Czaja et al.

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11. Regarding Claim 8, Czaja et al disclose using acoustic impulse reflection imaging for the measurement of physical and geometric features of a patient's airway (p. 505, Paragraph 2). However, Sexton et al teaches the use of Magnetic Resonance Imaging (MRI) to collect internal physical parameters of the throat airway of at least one other patient (Column 11, Lines 40-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the MRI method of Sexton et al to the data collection method of Czaja et al because this would create a data collection system that could function with two separate imaging modalities and would increase flexibility and accuracy for patients.

12. Regarding Claims 13 and 14, Sexton et al discloses a personal computer that works in conjunction with the disclosed method for improving lung delivery of pharmaceutical aerosols (Column 11, Lines 24-34).

13. Claim 9 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., *Acoustic Measurement of Subglottic Stenosis*; Ann Otol Rhinol Laryngol 105: 1996, in view of Stapleton et al, *On the Suitability of e-Turbulence Modeling for Aerosol Dispersion on the Mouth and Throat: A Comparison with Experiment*; Journal of Aerosol Science; 2000, Vol. 31, No. 6, pp 739-749.

14. Regarding Claim 9 and 12, Czaja et al and Sexton et al disclose a method for improving lung delivery of pharmaceutical aerosols and a method for measuring physical and geometric features of an airway using acoustic impulse reflection imaging as cited above. However, Stapleton et al disclose the use of a laboratory model that is a

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reconstruction of a previously measured throat (p. 741, Paragraph 7). Additionally, Stapleton et al disclose that the trachea is often modeled as a nearly cylindrical tube and that its length and diameter are well studied (p. 742, Paragraph 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al, Sexton et al and Stapleton et al because all of the inventions are in the field of imaging and modeling the dynamics of air movement in the throat and the construction of three dimensional, cylindrically-based laboratory models is a common method of conducting air movement research.

15. Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., *Acoustic Measurement of Subglottic Stenosis*; Ann Otol Rhinol Laryngol 105: 1996, in view of Zhou et al; *Measurement of upper airway movement by acoustic reflection*; Annals of Biomedical Engineering; 1995, Vol. 23, No. 1, pp. 85-94.

16. Regarding Claim 10, Czaja et al and Sexton et al disclose a method for improving lung delivery of pharmaceutical aerosols and a method for measuring physical and geometric features of an airway using acoustic impulse reflection imaging as cited above. However, Zhou et al disclose a curve fitting method used to aid in analysis of the geometric mapping of the throat through data collected with acoustic reflection imaging (Page 91). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al, Sexton et al and Zhou et al because all of the inventions are directed towards mapping of the

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geometric parameters of the throat, and a curve fitting method provides a way to give a continuous model of throat geometry for further experimentation and modeling.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lane, US Patent Number 6,139,504A.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Glass, US Patent Number 5,902,237A.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Adjei et al, WO 0174247 A2.

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Taylor, US Patent Number 6,709,397 B2.

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Unger, US Patent Number 6,315,981 B1.

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shokrollahi et al, US Patent Number 6,200,266 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin M. Lateef can be reached on (571)270-1493. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NLE 6/3/2009

/Marvin M. Lateef/

Supervisory Patent Examiner, Art Unit 4136